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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,765	01/05/2004	Pierluca Lombardi	03-728	2275
34704	7590	12/09/2008	EXAMINER	
BACHMAN & LAPOINTE, P.C. 900 CHAPEL STREET SUITE 1201 NEW HAVEN, CT 06510			GILBERT, ANDREW M	
			ART UNIT	PAPER NUMBER
			3767	
			MAIL DATE	DELIVERY MODE
			12/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/751,765	LOMBARDI, PIERLUCA
	<b>Examiner</b>	<b>Art Unit</b>
	ANDREW M. GILBERT	3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 05 November 2008.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 13, 15, 16, 18-21 and 23-27 is/are pending in the application.  
 4a) Of the above claim(s) 19 and 20 is/are withdrawn from consideration.  
 5) Claim(s) 27 is/are allowed.  
 6) Claim(s) 13, 15, 16, 21 and 23-26 is/are rejected.  
 7) Claim(s) 18 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 05 January 2004 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____ .

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/5/2008 has been entered.

### ***Acknowledgments***

1. This office action is in response to the reply filed on 11/5/2008.
2. In the reply, the Applicant amended claims 13 and 21 and added new claim 27 – incorporating subject matter from claim 18 that was previously indicated as allowable but depending from a rejected claim. Claims 19-20 were previously withdrawn.
3. Thus, claims 13, 15-16, 18, 21, 23-27 are pending for examination.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 13, 21, 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Treu (5630935).

6. Treu discloses an apparatus for regulating pressure applied during a medical procedure, comprising: an inelastic housing (Fig 4a,b) enclosing an inner volume, the housing having a first and second end (respective ends of syringe 135) wherein the housing (135) comprises a cylindrical inelastic housing enclosing the inner volume and a plunger (135); an aperture (opening of 138, 150 of syringe 135) in the housing for conveying pressure from the housing during medical procedure, and a pressure-operated valve (78) coupled between the inner volume of the housing and a space outside of the inner volume of the housing for allowing pressure to escape from the inner volume of the housing through the valve when pressure in the housing exceeds a threshold, whereby the valve releases pressure from within the inner volume of the housing (col 9, Ins 56-67); wherein the pressure-operated valve is adapted to allow selection of the threshold, during use, from a plurality of different pre-set thresholds (130; 144; col 9, Ins 56-67; wherein the user controls the force and thus the threshold via the adjustment member – additionally see Response to Arguments); wherein the pressure-operated valve comprises: an opening (opening of 136 that contacts diaphragm 140) in the housing; a plunger (140) disposed within the inner volume of the housing; a spring (144) disposed within the inner volume of the housing, wherein the spring is positioned between the second end of the housing and the plunger (Fig 4a-b), wherein the plunger in a rest position is between the opening and the aperture (Fig 4a-b), a pressure operated valve communicated with the inner volume of the housing and adapted to release pressure from the inner volume when pressure in the inner volume is above a threshold (Fig 4a-b; col 9, Ins 56-67; wherein when pressure rises the plunger

140 moves allowing fluid to move into 136 thus releasing pressure); wherein the threshold is set by a spring exerting a force which must be overcome to exceed the threshold (col 9, lns 56-67), and further comprising a movable member (140) which can be positioned between at least two different positions corresponding to different forces of the spring which must be overcome to exceed the threshold (col 9, lns 56-67); wherein the movable member only causes pressure to be released once the force is overcome (col 9, lns 56-67). Additionally, see Response to Arguments below.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 13, 15-16, 21, 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (4623335) in view of Treu (5630935). Jackson discloses an apparatus for regulating pressure applied during a medical procedure, comprising: an inelastic housing (24) enclosing an inner volume, the housing having a first and second end (respective ends of syringe 24 and 26) wherein the housing (24) comprises a cylindrical inelastic housing enclosing the inner volume and a plunger (25); an aperture (18) in the housing for conveying pressure from the housing during medical procedure, and a pressure-operated valve (22; Fig 2) coupled between the inner volume of the housing and a space outside of the inner volume of the housing for allowing pressure to

escape from the inner volume of the housing through the valve when pressure in the housing exceeds a threshold, whereby the valve releases pressure from within the inner volume of the housing (Figs 1-4; col 5, Ins 32-col 6, Ins 3); wherein the pressure operate valve comprises and opening (52), a plunger (60) disposed within the inner volume of the housing; a spring (52) disposed within the inner volume of the housing, wherein the spring is positioned between the second end of the housing and the plunger (Fig 2), wherein the plunger in a rest position is between the opening and the aperture (Fig 2), and wherein as fluid is inserted into the inner volume of the housing via the aperture, increased pressure within the inner volume of the housing moves the plunger toward the opening (Figs 1-4; col 5, Ins 32-col 6, Ins 3); wherein the opening is positioned in a side of the housing providing access to the inner volume of the housing (52; Fig 2), wherein at normal pressure the opening is closer to the second end than the plunger and wherein as pressure within the inner volume of the housing increases so as to move the plunger past the opening (Figs 1-4), the pressure within the inner housing is released through the opening (Figs 1-4; col 5, Ins 32-col 6, Ins 3); wherein the threshold is set by a spring exerting a force which must be overcome to exceed the threshold (Figs 1-4; col 5, Ins 32-col 6, Ins 3).

9. However, Jackson does not disclose that the pressure operated valve is adapted to allow selection of the threshold, during use, from a plurality of different pre-set thresholds; wherein a movable member which can be positioned between at least two different positions corresponding to different forces of the spring which must be overcome to exceed the threshold. Treu teaches that it is known to have a pressure

operated valve adapted to allow selection of the threshold during use from a plurality of different thresholds (130; 144; col 9, lns 56-67; wherein the user controls the force and thus the threshold via the adjustment member) and a movable member (140) which can be positioned between at least two different positions corresponding to different forces of the spring which must be overcome to exceed the threshold (col 9, lns 56-67) for the purpose of controlling the threshold value. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the spring system as taught by Jackson with the spring system adapted to allow selection of the threshold as taught by Treu for the purpose of controlling the threshold valve.

***Response to Arguments***

10. Applicant's arguments filed 3/10/2008 have been fully considered but they are not persuasive.
11. The Applicant argues that Treu does not disclose a plurality of different pre-set thresholds. Rather, the threshold is continuous and not pre-set.
12. In response to applicant's argument, the Examiner notes that "pre-set" is defined as "to set in advance" by Webster's dictionary. So the claim requires a plurality of thresholds set in advance. The device of Treu has an adjustment member (130) that screws clockwise or counterclockwise relative to housing (153) to thereby adjust the force that the pressure relief spring (144) applies to the plastic plunger (142) and elastomeric diaphragm (140). This adjustment changes the threshold level for pressure relief during use. The Examiner contends that the selection of the spring and selection of the range the adjustment member can be rotated to adjust the force of the spring -

constitutes a plurality of pre-set thresholds. Before use, due to the selection of the spring and properties of the adjustment member, the device of Treu has a plurality of available thresholds that the user can set the device to during use. The Examiner suggests defining the pre-set thresholds as being *discrete* thresholds. Treu discloses a continuous range of thresholds, but they are not discrete – although Treu could obviously be made to adapted to allow selection from discrete thresholds (e.g. one full rotation of the adjustment member will always produce a discrete threshold, a second full rotation of the member will always produce a second discrete threshold, etc...). The Examiner also suggests positively reciting the property of the valve, rather than the valve just being “adapted to” to strengthen the claim language. Lastly, the Examiner suggests structurally defining the valve so that automated valves controlled by users via processors (e.g. a user can select the threshold that the valve will release fluid at via an input into a processor and a plurality of thresholds are available - see Kraus et al (5928182)) cannot read on the claims.

***Conclusion***

2. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 Form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/  
Examiner, Art Unit 3767  
/Kevin C. Sirmons/  
Supervisory Patent Examiner, Art Unit 3767